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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
08/928,272	09/12/1997	MICHAEL J. ISKRA	P-3818	9434
7590 RICHARD J RODRICK BECTON DICKINSON AND COMPANY 1 BECTON DRIVE FRANKLIN LAKES, NJ 074171880			EXAMINER MATTER, KRISTEN CLARETTE	
			ART UNIT 3771	PAPER NUMBER
			MAIL DATE 04/26/2011	DELIVERY MODE PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

**Office Action Summary****Application No.**

08/928,272

**Applicant(s)**

ISKRA, MICHAEL J.

**Examiner**

KRISTEN C. MATTER

**Art Unit**

3771

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 30 March 2011.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1 and 5-9 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1 and 5-9 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SG-06)  
Paper No(s)/Mail Date \_\_\_\_\_

- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

### DETAILED ACTION

This Action is in response to the Appeal Brief filed on 3/30/2011. No claims have been amended, added or cancelled. Therefore, claims 1 and 5-9 are currently pending in the instant application.

In view of the Appeal Brief filed on 3/30/2011, **PROSECUTION IS HEREBY REOPENED**. New grounds of rejection are set forth below.

To avoid abandonment of the application, appellant must exercise one of the following two options:

(1) file a reply under 37 CFR 1.111 (if this Office action is non-final) or a reply under 37 CFR 1.113 (if this Office action is final); or,

(2) initiate a new appeal by filing a notice of appeal under 37 CFR 41.31 followed by an appeal brief under 37 CFR 41.37. The previously paid notice of appeal fee and appeal brief fee can be applied to the new appeal. If, however, the appeal fees set forth in 37 CFR 41.20 have been increased since they were previously paid, then appellant must pay the difference between the increased fees and the amount previously paid.

A Supervisory Patent Examiner (SPE) has approved of reopening prosecution by signing below:

/Justine R Yu/  
Supervisory Patent Examiner, Art Unit 3771

### **Claim Rejections - 35 USC § 103**

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

**Claims 1, 6, and 9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Applicant's Admitted Prior Art (Figures 1-2) in view of Finney et al. (US 4,358,425, herein referred to as "Finney").**

Regarding claim 1, Applicant discloses a prior art device in Figures 1-2 that includes a one piece collection container assembly comprising an elongate tubular housing (12) having opposed first and second ends (at 24 and 36), a solid partition contacting a sidewall (12) of the tube forming a closed bottom (26) and positioned within said housing between the first and second ends (see Figures 1-2), said housing defining a volume for specimen collection and containment therein between said first end and said partition (see page 8, line 6), said second end forming a false bottom (32) comprising a bottom end below said partition comprising an annular skirt (28) comprising an opening (36) therein.

The sole difference between the admitted prior art and the instant invention is the bottom of the tube being semi-spherical. However, absent a critical teaching and/or a showing of unexpected results from the tube having a semi-spherical bottom examiner contends that such a modification is an obvious design consideration to one of ordinary skill in the art as a mere change in shape that does not patentably distinguish an invention over the prior art. Changing the

bottom to a semi-spherical shape would allow the tube to be compatible with common standard clinical equipment and instrumentation depending on the exact intended use of the tube. In addition, Finney teaches a specimen collection tube with a bottom surface through which fluid is able to pass and having a semi-spherical shape (see Figure 1). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have provided the admitted prior art device with a semi-spherical false bottom as taught by Finney depending on the intended use of the device or to allow compatibility with standard clinical centrifuge equipment (abstract of Finney discusses how such a shape allows the tube to be used in the cavity of a centrifuge rotor) because such a shape was well known at the time of the invention as suitable for such uses. Such a modification would involve substitution of a well known shape (i.e., tube having a semi-spherical bottom) into a well known device to yield predictable results that do not patentably distinguish an invention over the prior art and would have been obvious to try from a finite number of standard centrifuge tube bottom shapes compatible with clinical equipment..

Regarding claim 6, the partition disclosed by the admitted prior art is arcuate in shape (see Figures 1-2).

Regarding claim 9, the admitted prior art is silent as to the dimensions of the container. However, absent a critical teaching and/or showing of unexpected results from making the container the claimed dimensions, examiner contends that it is an obvious design consideration to one of ordinary skill in the art to make the admitted prior art container the claimed dimensions because those dimensions are commonly used for blood/specimen collection containers. In addition, it appears as though the prior art device would perform equally well with the claimed

dimensions. See also *In re Rose*, 220 F.2d 459, 463, 105 USPQ 237, 240 (CCPA 1955), in which the court held that mere changes in size do not patentably distinguish an invention over the prior art.

**Claims 5, 7, and 8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Applicant's Admitted Prior Art (Figures 1-2) and Finney, as applied to claims 1, 6, and 9 above, and further in view of Burns (US 5,458,854).**

Regarding claim 5, the admitted prior art lacks the partition being arcuate in shape. However, absent a critical teaching and/or a showing of unexpected results from the partition being arcuate (as opposed to conical), examiner contends that such a modification is an obvious design consideration to one of ordinary skill in the art as a mere change in shape without a change in function that does not patentably distinguish an invention over the prior art. In addition, Burns discloses a similar collection container with an arcuate solid partition (38; see Figure 1). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the shape of the admitted prior art device to be arcuate as taught by Burns in order to effectively separate specimens in the container using a well known method/shape of tube. Furthermore, it appears as though the tube of the admitted prior art would work equally well with any shape of partition so long as specimen could be retained and separated. Such a modification involves the mere substitution of one well known solid partition shape for another to yield predictable results that do not patentably distinguish an invention over the prior art.

Regarding claims 7 and 8, the admitted prior art is silent as to the material of the tube. However, Burns discloses, in a similar collection container, that the tube housing can be made of a thermoplastic polymer such as polyvinyl chloride (column 5, lines 43-50). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have made the admitted prior art tube from polyvinyl chloride as taught by Burns in order to use a well known effective material for storing specimen samples. Such a modification involves the mere use of a well known material in a well known device to yield predictable results that do not patentably distinguish an invention over the prior art. See also *In re Leshin*, 227 F.2d 197, 125 USPQ 416 (CCPA 1960), in which the selection of a known material based on its suitability for its intended use supported a prima facie case of obviousness.

### **Response to Arguments**

Applicant's arguments, filed 3/30/2011, with respect to the rejection(s) of claim(s) 1 and 5-9 under Burns in view of Finney have been fully considered and are persuasive. Therefore, the rejection has been withdrawn. However, upon further consideration, a new ground(s) of rejection is made in view of applicant's admitted prior art.

Specifically, Burns discloses a cap for allowing the device to stand upright unsupported and it would not simply involve a mere design consideration to change the cap properties to fit a semi-spherical false bottom.

Likewise, applicant's arguments, filed 3/30/2011, with respect to the rejection(s) of claim(s) 1 and 5-9 under Dreier in view of Saunders and Finney have been fully considered and are persuasive. Therefore, the rejection has been withdrawn.

Particularly, the cited portion of Saunders relating to centrifuge tubes being typically “flat or slightly rounded” is used in a context that is not supportive of changing a false bottom shape (i.e., since the tube shape is discussed as relating to effects on material separation).

Examiner also notes that applicant’s argument that Finney fails to disclose a false bottom and thus would not be obvious to combine with Burns (and as it would now relate to the admitted prior art) is not convincing because Finney discloses a solid-walled collection tube with an opening in the bottom, same as the instant invention. Finney specifically states that the plug is made separately and subsequently inserted into the opening (column 2, lines 50-55), thus the manufacturing techniques for forming the semi-spherical false bottom wall were known at the time of the invention and it would have been obvious to one of ordinary skill in the art to use any well known false bottom tube shape in the prior art device for reasons discussed above. Whether the opening is subsequently filled with a plug is not a dispositive factor for or against using the reference to teach a well known collection tube shape with an open bottom that fits in standard centrifuge systems. In addition, examiner contends that even with the plug inserted, liquid is still able to be transferred through the bottom wall (via the needle) and thus, the wall can be considered a false bottom as broadest reasonably interpreted. Accordingly, one of ordinary skill in the art upon seeing the admitted prior art and Finney could find motivation to make the bottom wall/false bottom of the prior art semi-spherical as taught by Finney since both shapes fit in standard clinical equipment and use of one or the other is a mere change in shape without a change in function that is obvious to try from a finite number of standard collection tube shapes suitable for clinical use.



### **Conclusion**

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Hirth is cited as showing another tubular container with a smaller opening in a false bottom.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to KRISTEN C. MATTER whose telephone number is (571)272-5270. The examiner can normally be reached on Monday - Friday 9-4.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Justine Yu can be reached on (571) 272-4835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Kristen C. Matter/  
Examiner, Art Unit 3771

